

REMARKS

I. Status of the Claims

Claims 1-85 are pending. Claims 10, 22, 26-29, 31, 32, 34-49, 52-54, and 85 have been withdrawn from consideration under 37 C.F.R. § 1.142(b) as being directed to non-elected species. Applicants remind the Examiner of the duty under MPEP § 803.02 and 35 U.S.C. § 121 to extend the search to a reasonable number of non-elected species once the elected species is found allowable.

II. Incorporation by Reference

The Examiner has characterized the reference in Applicants' specification to G. Fonnum, J. Bakke and Fk. Hansen – Colloid Polym. Sci 271, 380-389 (1993) as improper because it attempts to incorporate essential material by reference to a non-patent publication. Applicants respectfully disagree.

The MPEP defines "essential material" as "that which is necessary [under 35 U.S.C. § 112] to (1) describe the claimed invention, (2) provide an enabling disclosure of the claimed invention, or (3) describe the best mode." MPEP § 608.01(p)(I)(A). Applicants submit that the representative polyether-polyurethanes described in the Fonnum et al. article are well known in the art, so that the omission from the specification of the specific recitation thereof would not raise any issues under 35 U.S.C. § 112, first paragraph. In fact, the court has held that "a patent need not teach, and preferably omits, what is well known in the art." *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 231 USPQ 81, 94 (Fed. Cir. 1986).

III. Rejection Under 35 U.S.C. § 112, Second Paragraph

The Examiner has rejected (1) claims 1 and 70-80 and (2) claims 55 and 56 under 35 U.S.C. § 112, second paragraph as indefinite because of the misspellings of amphiphilic and tetraalkylammonium, respectfully. Applicants have corrected the spellings in the foregoing amendment. Applicants note that claims 76 and 78 do not contain the word amphiphilic. Accordingly, these claims have not been amended. Withdrawal of the rejections is respectfully requested.

The Examiner has rejected claim 21 under 35 U.S.C. § 112, second paragraph as indefinite because it is unclear to the Examiner whether the parenthetical phrase "(8 mol of ethylene oxide)" is a required limitation of the claims. Applicants have amended claim 21 to recite "polyethylene glycol isostearate comprising 8 ethylene oxide units." Support for this amendment appears, for example, at page 10, lines 12-13 of the present specification.

IV. Rejection Under 35 U.S.C. § 103(a)

The Examiner has rejected claims 1-9, 11-21, 23-25, 30, 33, 50, 51, and 55-84 under 35 U.S.C. § 103(a) as unpatentable over U.S. Patent No. 5,925,341 to Cervantes et al. ("US '341") in combination with WO 99/36047 to Casperson et al. ("WO '047"). According to the Examiner, US '341 discloses oil-in-water nanoemulsions containing "nonionic amphiphilic lipids and aminated silicones wherein the oily globules have an

average size of less than or equal to 150nm." Office Action at page 4. The Examiner recognized that US '341 fails to teach a required element of Applicants' claims, namely at least one nonionic polymer comprising at least one hydrophobic block and at least one hydrophilic block. Office Action at page 5. The Examiner noted that column 12, lines 15-34 of US '341 discloses that the nanoemulsions thereof may contain thickeners.

In order to remedy the deficiency of US '341, the Examiner has cited WO '047 for its disclosure of "the use of polyether-polyurethane block copolymers in hair compositions for enhanced rheological and conditioning benefits." *Id.* The Examiner concluded that it would have been obvious "to add a nonionic block copolymer as taught by WO '047 to the nanoemulsion of US '341 with the reasonable expectation of obtaining enhanced rheological and hair conditioning benefits." *Id.* In addition, the Examiner stated, "[t]he nanoemulsion obtained by the combination of cited prior art containing the same components as instantly claimed in the same amounts would be expected to exhibit the same properties. Therefore, absent evidence to the contrary, the turbidity of the nanoemulsion is not considered critical to the invention." *Id.*

Applicants respectfully traverse this rejection.

To establish a prima facie case of obviousness, three basic criteria must be met, including that there must be some suggestion or motivation to modify the reference or to combine reference teachings and that there must be a reasonable expectation of success. The teaching or suggestion to make the claimed modification and the reasonable expectation of success must both be found in the prior art, not in applicant's disclosure. See MPEP § 2143 and cases cited therein. For at least the reason that the

references would have provided no motivation or reasonable expectation of success to reach Applicants' invention, the rejection is improper.

Absent Applicants' disclosure, the recitation of "thickeners" in US '341 would have provided no motivation for one to select the block copolymers of Applicants' claims. Moreover, US '341 lists several types of suitable thickeners in the passage immediately after that cited by the Examiner. See column 12, lines 34-44. None is the instantly claimed at least one nonionic polymer comprising at least one hydrophobic block and at least one hydrophilic block. Furthermore, none of the seven examples of US '341 includes a thickener. Absent Applicants' disclosure, there would have been no motivation to search for additional thickeners beyond those disclosed by US '341.

While WO '047 discloses the use of polyether-polyurethane polymers as a thickener, the polymers are for use in a two component (dye/developer) hair dye composition. There is no disclosure of using such polymers in emulsions or nanoemulsions or in the presence of considerable amounts of oil. The composition of WO '047 is water based. See page 6, line 23. The polyether-polyurethane is present in one or both components such that the hair dye composition resulting from mixing the two components is thick, even though the individual unmixed components containing polyether-polyurethane may both be thin, pourable liquids. See last line of abstract, page 4, lines 11-23, and page 5, lines 13-15. As such, the polyether-polyurethane is specific to the aqueous based hair dye composition of WO '047, and one would have had no motivation to use the polyether-polyurethane in the completely different environment (oil-in-water emulsions) of US '341. Nor would one have expected that the polyether-polyurethane would function successfully in that different environment.

Furthermore, one would not have expected that using polyether-polyurethane copolymers would produce stable and transparent emulsions. Contrary to the Examiner's remarks regarding turbidity, one would have had no expectation that using water-soluble or water-dispersible polymers would have produced stable and transparent nanoemulsions. In fact, Applicants have found that using CARBOPOL ULTREZ, for example, instead of Aculyn 46 in "a composition which is not thickened, not transparent . . . and not stable on storage." Specification at page 54, lines 20-21. Withdrawal of the rejection is respectfully requested.

V. Unexpected Results

The Examiner stated at page 6 of the Office Action that Applicants have a burden of demonstrating unexpected results. Applicants are under no such burden. On the contrary, the Examiner bears the initial burden of presenting a prima facie case of unpatentability. If that burden is met, the burden of coming forth with evidence or argument then shifts to the applicant. *In re Piasecki*, 223 USPQ 785 (Fed. Cir. 1984). However, Applicants submit that the Examiner has not established a prima facie case of unpatentability. In such a situation, Applicants are entitled to a patent grant.

VI. Double Patenting Rejection

The Examiner has rejected Claims 1-9, 11-13, 17-21, 23-25, 30, 33, 50, 51, 55-65, and 70-84 over claims 1-5, 14-25, 29-31, and 33 of copending Application No. 09/903,768. While Applicants disagree with the basis for this rejection, Applicants

submit herewith a Terminal Disclaimer in order to obviate this rejection and expedite prosecution of this application.

VII. Objections to Claims

The Examiner has noted that claims 70-74, 77, 78, 80, and 81 are potentially objectionable under 37 C.F.R. § 1.75 as substantial duplicates of claims 1, 2, 75, and 76. As set forth in MPEP § 706.03(k) substantially duplicate claims are those covering "the same thing, despite a slight difference in wording." Applicants submit that the potentially objectionable claims do not cover the same thing as claims 1, 2, 75, and 76.

For example, the preambles of claims 70-74 recite compositions that do not necessarily have the same scope as the compositions of claim 75. Moreover, claim 1 is directed to a nanoemulsion while claims 70-74 are directed to various compositions comprising a nanoemulsion. Withdrawal of this potential objection is respectfully requested.

CONCLUSION

In view of the foregoing amendments and remarks, Applicants respectfully request reconsideration and reexamination of this application, and the timely allowance of the pending claims.

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If there is any fee due in connection with the filing of this amendment, please
charge the fee to our Deposit Account No. 06-0916.

Respectfully submitted,

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APPENDIX

Version With Markings Showing Changes Made Pursuant to
37 C.F.R. § 1.121(c)(1)(ii)

1. (Amended) An oil-in-water nanoemulsion comprising oil globules with an average size of less than 150nm comprising at least one oil, at least one [amphiphilic] amphiphilic lipid, and at least one nonionic polymer comprising at least one hydrophobic block and at least one hydrophilic block.

21. (Amended) A nanoemulsion according to claim 19, wherein said nonionic amphiphilic lipids are chosen from:

- polyethylene glycol isostearate [8 mol of ethylene oxide] comprising 8 ethylene oxide units,
- diglycerol isostearate,
- polyglycerol monolaurate, polyglycerol monostearate, and polyglycerol distearate which comprise 10 glycerol units,
- sorbitan oleate, and
- sorbitan isostearate.

55. (Amended) A nanoemulsion according to claim 30, wherein said cationic amphiphilic lipids of formula (IV) are chosen from [tetraalkylammonium] tetraalkylammonium chlorides.

56. (Amended) A nanoemulsion according to claim 55, wherein said [tetraalkylammonium] tetraalkylammonium chlorides are chosen from

dialkyldimethylammonium chlorides, and alkyltrimethylammonium chlorides, wherein said alkyl portion comprises from 12 to 22 carbon atoms.

70. (Amended) A composition for topical use chosen from cosmetic compositions and dermatopharmaceutical compositions, wherein said composition for topical use comprises a nanoemulsion comprising oil globules with an average size of less than 150nm comprising at least one oil, at least one [amphiphilic] amphiphilic lipid, and at least one nonionic polymer comprising at least one hydrophobic block and at least one hydrophilic block.

71. (Amended) A composition for caring for a keratin material chosen from body skin, facial skin, mucous membranes, the scalp, the hair, the nails, the eyelashes, and the eyebrows comprising a nanoemulsion comprising oil globules with an average size of less than 150nm comprising at least one oil, at least one [amphiphilic] amphiphilic lipid, and at least one nonionic polymer comprising at least one hydrophobic block and at least one hydrophilic block.

72. (Amended) A composition for washing a keratin material chosen from body skin, facial skin, mucous membranes, the scalp, the hair, the nails, the eyelashes, and the eyebrows comprising a nanoemulsion comprising oil globules with an average size of less than 150nm comprising at least one oil, at least one [amphiphilic] amphiphilic lipid, and at least one nonionic polymer comprising at least one hydrophobic block and at least one hydrophilic block.

73. (Amended) A cosmetic make up composition for a keratin material chosen from body skin, facial skin, mucous membranes, the scalp, the hair, the nails, the eyelashes, and the eyebrows comprising a nanoemulsion comprising oil globules

with an average size of less than 150nm comprising at least one oil, at least one [amphiphilic] amphiphilic lipid, and at least one nonionic polymer comprising at least one hydrophobic block and at least one hydrophilic block.

74. (Amended) A cosmetic make-up-removing composition for a keratin material chosen from body skin, facial skin, mucous membranes, the scalp, the hair, the nails, the eyelashes, and the eyebrows comprising a nanoemulsion comprising oil globules with an average size of less than 150nm comprising at least one oil, at least one [amphiphilic] amphiphilic lipid, and at least one nonionic polymer comprising at least one hydrophobic block and at least one hydrophilic block.

75. (Amended) A non-therapeutic care process for a keratin material comprising applying to said keratin material a nanoemulsion comprising oil globules with an average size of less than 150nm and comprising at least one oil, at least one [amphiphilic] amphiphilic lipid, and at least one nonionic polymer comprising at least one hydrophobic block and at least one hydrophilic block.

77. (Amended) A non-therapeutic care process for a keratin material comprising applying to said keratin material a composition for topical use chosen from cosmetic compositions and dermatopharmaceutical compositions, wherein said composition for topical use comprises a nanoemulsion comprising oil globules with an average size of less than 150nm and comprising at least one oil, at least one [amphiphilic] amphiphilic lipid, and at least one nonionic polymer comprising at least one hydrophobic block and at least one hydrophilic block.

79. (Amended) A process for thickening oil-in-water nanoemulsions comprising including at least one nonionic polymer comprising at least one hydrophobic

block and at least one hydrophilic block in said nanoemulsions comprising oil globules with an average size of less than 150nm and comprising at least one oil and at least one [amphiphilc] amphiphilic lipid.

80. (Amended) An oil-in-water nanoemulsion comprising oil globules with an average size of less than 150nm comprising at least one oily phase, at least one [amphiphilc] amphiphilic lipid, and at least one nonionic polymer comprising at least one hydrophobic block and at least one hydrophilic block.